PTO/SB/08a (11-07)

Approved for use through 11/30/2007. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

e required to respond to a collection of information unless it contains a valid OMR control number

Under the Paperwork Reduction AN Substitute for form 1449A/PTO

INFORMATION DISCLOSURE

STATEMENT BY APPLICANT

Complete if Known

Application Number 10/539,208

Filing Date MAY 24, 2006

First Named Inventor DAVID RAAB

Art Unit 1644

Examiner Name NOT YET ASSIGNED

Attorney Docket Number B&B-135

(Use as many sheets as necessary)

Sheet 1 of 4

U. S. PATENT DOCUMENTS							
Examiner Initials*	Cite No.1	Document Number Number-Kind Code ^{2 (if known)}	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
	1	us- 2002/0072864A1	06/13/2002	LACROIX et al.			
		US-					
		US-			-		
		US-					
		US-					
		US-					
		US-					
		US-					
		US-					
		US-					
		US-	,				
		US-					
		US-					
		US-					
		US-					
		US-					
		US-					
		US-					

	FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No.1	Foreign Patent Document Country Code ³ "Number ⁴ "Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Τ ⁶			
	2	WO 98/34640	08/13/1998	MERCK & CO., INC.					
	3	WO 00/42560	07/20/2000	MAXYGEN, INC.					
	4	DE 199 14 808 A1	10/19/2000	RAUHE, HILMAR					
	5	WO 01/16810 A2	03/08/2001	THE EUROPEAN MOLECULAR BIOLOGY LAB.					
	6	EP 1 156 112 A1	11/21/2001	GENEART GMBH					

$\overline{}$	· · · · · · · · · · · · · · · · · · ·		
Examiner		Date	
Signature		Considered	

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS American Legality. Inc.

| American Legality | A

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. Applicant is to place a check mark here if English language Translation is attached.

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Apt of 1995 no Persons are required to respond to a collection of information unless it contains a valid OMR control number

Substitute for form 1449A/PTO				Complete if Known			
		Application Number	10/539,208				
I	NFORMATION DISC	CLC	SURE	Filing Date	MAY 24, 2006		
	STATEMENT BY AF	PL	ICANT	First Named Inventor	DAVID RAAB		
				Art Unit	1644		
(Use as many sheets as necessary)				Examiner Name	NOT YET ASSIGNED		
Sheet	2	of	4	Attorney Docket Number	B&B-135		

	U. S. PATENT DOCUMENTS							
Examiner Initials*	Cite No.1	Document Number Number-Kind Code ^{2 (if known)}	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear			
		US-						
		US-						
		US-						
		US-						
		US-						
		US-						
		US-						
		US-						
		US-						
		US-						
		US-						
		US-						
		US-						
		US-						
		US-						
		US-						
		US-						
		US-						

	FOREIGN PATENT DOCUMENTS								
Examiner	Cite	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	- 6			
Initials*	No.'	Country Code ³ "Number ⁴ "Kind Code ⁵ (if known)	IVIIVI-DD-1111	Applicant of Cited Document	or Relevant Figures Appear	ľ			
				TRUSTEES OF THE					
	7	WO 02/29088 A2	04/112002	UNIVERSITY OF					
				PENNSYLVANIA					
	↓		ļ						

		
Examiner	Date	
Signature	Considered	
	1	1

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. The Police that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Under the Paperwork Reduction Apt of 1995 no Persons are required to respond to a collection of information unless it contains a valid OMR control number.

Subs	titute for form 1449B/PTO			Complete if Known			
				Application Number	10/539,208		
INI	FORMATION DIS	CLOS	URE	Filing Date	MAY 24, 2006		
ST	ATEMENT BY AF	PLIC	ANT	First Named Inventor	DAVID RAAB		
				Art Unit	1644		
	(Use as many sheets as ned	essary)		Examiner Name	NOT YET ASSIGNED		
Sheet	3	of	4	Attorney Docket Number	B&B-135	$\overline{}$	

	NON PATENT LITERATURE DOCUMENTS						
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²				
		HOOVER DAVID M ET AL: "DNAWorks: an automated method for designing					
	8	oligonucleotides for PCR-based gene synthesis" NUCLEIC ACIDS RESEARCH, OXFORD UNIVERSITY PRESS, SURREY, GB, Bd. 30, Nr. 10, 15. Mai 2002 (2002-05-15).					
		CHRISLAINE WITHERS-MARTINEZ ET AL: "PCR-based gene synthesis as an efficient					
		approach for expression of the A+T-rich malaria genome" PROTEIN ENGINEERING,					
	9	OXFORD UNIVERSITY PRESS, SURREY, GB, Bd. 12, Nr. 12, December 1999 (1999-12). WILLIAMS D P ET AL: "DESIGN, SYNTHESIS AND EXPRESSION OF A HUMAN					
		INTERLEUKIN-2 GENE INCORPORATING THE CONDON USAGE BIAS FOUND IN					
	10	HIGHLY EXPRESSED ESCHERICHIA COLI GENES" NUCLEIC ACIDS RESEARCH,					
		OXFORD UNIVERSITY PRESS, SURREY, GB, Bd. 16, Nr. 22, 25 November 1988 (1988-11-25).					
		LEE F ET AL: "ISOLATION OF COMPLEMENTARY DNA FOR A HUMAN					
	11	GRANULOCYTE-MACROPHAGE COLONY-STIMULATING FACTOR BY FUNCTIONAL EXPRESSION IN MAMMALIAN CELLS" PROCEEDINGS OF THE NATIONAL ACADEMY					
	ļ	OF SCIENCES OF THE UNITED STATES OF AMERICA, Bd. 82, Nr. 13, 1985. MEAZZA R ET AL: "Identification of a novel interleukin-15 (IL-15) transcript isoform					
	12	generated by alternative splicing in human small cell lung cancer cell lines." ONCOGENE. 16 MAY 1996, Bd. 12, Nr. 10, 16. Mai 1996 (1996-05-16).					
	10	SINCLAIR, G. & CHOY, F.Y.: Synonymous codon usage bias and the expression of human glucocerebrosidase in the methylotrophic yeast, Pichia pastoris. Protein Expr. Purif.					
	13	(October 2002) 26 (1) 96-105.					
	14	HAMDAN, F.F. et al.: Codon optimization improves heterologous expression of a Schistosoma mansoni cDNA in HEK293 cells. Parasitol. Res. (June 2002) 88 (6) 583-6.					
		DEML, L. et al.: Multiple effects of codon usage optimization on expression and					
	15	immunogenicity of DNA candidate vaccines encoding the human immunodeficiency virus type 1 Gag protein. J. Virol. (2001) 75 (22) 10991-1001					
	10	Type 1 day protein. 3. Vilol. (2001) 13 (22) 10331-1001	L				

Examiner	Date]
Signature	Considered	l ·

^{*} EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not

considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Under the Paperwork Reduction Apt of 1995 no Persons are required to respond to a collection of information unless it contains a valid OMR control number. Substitute for form 1449B/PTO Complete if Known **Application Number** 10/539,208 INFORMATION DISCLOSURE Filing Date MAY 24, 2006 STATEMENT BY APPLICANT

4

(Use as many sheets as necessary)

Sheet

4

First Named Inventor DAVID RAAB Art Unit 1644 **Examiner Name** NOT YET ASSIGNED Attorney Docket Number B&B-135

	NON PATENT LITERATURE DOCUMENTS						
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²				
	16	HALE, R.S. & THOMPSON, G.: Codon optimization of the gene encoding a domain from human type 1 neurofibromin protein results in a threefold imporvement in expresion level in Escherichia coli. Protein Expr. Purif. (1998) 12 (2) 185-8.					
	17	HUMPHREYS, D.P. et al.: High-level periplasmic expression in Escherichia coli using a eukaryotic signal peptide: importance of codon usage at the 5' end of the coding sequence. Protein Expr. Purif. (2000) 20 (2) 252-64					
	18	KIM, C.H. et al.: Codon optimization for high-level expression of human erythropoietin (EPO) in mammalian cells. Gene (1977) 199 (1-2) 293-301					

,				
Examiner		Date		
		24.0	[
Signature		Considered		

^{*} EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not

considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.